

REMARKS

Claims 108-111 have been canceled. Claims 66-68 and 98-103 have been amended. Claims 66-68 and 70-108 are currently pending in the application.

Claims 66-68 and 98-103 have been amended to specify that the reversed cubic phase structured fluid and the pharmaceutical active make up a single thermodynamic phase. Support for this can be found in paragraph [0017] of the published application.

Claim 72 has been amended to address the spelling error identified in the office action.

In response to the first rejection under 35 U.S.C. 112, first paragraph, claims 68 and 101 have been amended to eliminate the reference to "body temperature", and claims 108-111 have been canceled. While the applicant is of the opinion one of ordinary skill in the art would be aware of body temperature and that the application provides adequate support for the claims, the amendments and cancelations have been provided to accelerate prosecution to grant. The applicant retains the right to pursue these claims or other claims supported by the patent specification in one or more continuing applications.

In response to the second rejection under 35 U.S.C. 112, first paragraph, it is noted that the concept of having a subset of the pharmaceutical active, in addition to being less than 5% by weight soluble in soybean oil (as specified in base claims 66-68), also being greater than 5% soluble in an essential oil is taught when the totality of paragraph [0235] and [0236] and the table therebetween are considered. Here it is stated that "The ability of a number of these GRAS oils to solubilize difficultly soluble drugs has been demonstrated by solubilizing paclitaxel in the oils", i.e., paragraph [0235] makes clear that the teaching is for a number of difficultly soluble drugs, not just paclitaxel. Furthermore, data in the table, and the surrounding paragraphs make clear that the table is exemplary of a number of GRAS oils, not just those in the table.

Claims 66, 68, 70, 71, 73, 74, 83, 84, 86, 87, 90, 92, 95, 97, 98, 100-104, 106, 108, and 110 were rejected as being anticipated by Anderson as evidenced by U.S. Patent 5,026,548 to Evans, Burdock (Food and Color Additives, 1997), and Muldoon (Systematic Organic Chemistry, 1957). Claims 67, 72, 75-82, 85, 88, 89, 91, 93, 94, 96, 99, 105, 107, 109, and 111 were rejected as being obvious over Anderson as evidenced by Evans, Burdock, and Muldoon.

Both rejections are based on a misunderstanding of the WO 99 12640 reference to Anderson and are traversed.

As recognized by the Examiner, the inventor of the present application is the inventor of the Anderson reference (Lyotropic Therapeutics is the owner of the present application and all US and foreign patents relating to the Anderson reference). David Anderson is a qualified expert in the subject matter pertaining to the present application and has previously submitted declarations in the application on December 15, 2009; March 26, 2009; and October 14, 2008.

The Examiner relies on Anderson as teaching the requirement of having the pharmaceutical active that is less than 5% by weight soluble in soybean oil solubilized in the reversed cubic phase structured fluid. However, this reliance is in error, as Anderson does not demonstrate such a teaching.

As indicated in the concurrently filed declaration of David Anderson, the Anderson patent describes "metastable" solutions within the coated particles. In Anderson, the coating basically assists in keeping the compound within the particle; however, the compound is clearly not solubilized within the reversed cubic phase as is required in the claims. To further highlight this distinction, claims 66-68 and 98-103 require that the pharmaceutical active and the structured fluid make up a single thermodynamic phase. Anderson clearly falls outside this requirement as is evidenced by statements made in Examples 36 and 37 and the concurrently filed declaration of David Anderson.

The Evans, Burdock and Muldoon references cannot provide any evidence to the contrary of what is shown and described in Anderson, therefore, the anticipation claim should be withdrawn. Moreover, the Evans, Burdock and Muldoon references would not make any of the claims obvious over Anderson as none of these references show a pharmaceutical active solubilized in a reversed cubic phase structure fluid in a manner that a single thermodynamic phase is formed.

With regard to "anisole" being an essential oil or synthetic, to accelerate prosecution independent claims have been specifically amended to exclude anisole. However, as noted in the previous response and declarations, and in the current declaration, anisole used in pharmaceutical formulations is a synthetic.

In view of the above and the concurrently filed declaration, claims 66-68 and 70-108 should now be reconsidered and allowed at an early dated.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; e-mail: mike@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



Michael E. Whitham
Reg. No. 32,635

Whitham, Curtis, Christofferson & Cook, P.C.
11491 Sunset Hills Road, Suite 340
Reston, VA 20190
703-787-9400 (Telephone)
703-787-7557 (Facsimile)
Customer No. 30743